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TITLE: "Serum and Exudate Calcitonin Precursors as Predictors of Wound Infection and Dehiscence in Wartime Penetrating Injuries"

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13. SUPPLEMENTARY NOTES

14. ABSTRACT To date, we have enrolled 148 patients into the study that have either been wounded in Iraq or Afghanistan and 5 control tissue patients who hae had their patella tendon repaired and donated pieces of the Autologous tendon.

15. SUBJECT TERMS
War Wounds, Blast Injuries, Infection, Debridement, Procalcitonin, Cytokines

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INTRODUCTION:

This controlled variable study will demonstrate that ProCT and other cytokines are detectable in wound exudate. It will also determine the sensitivity, specificity, and both positive and negative predictive values of serum and exudate ProCT/cytokines with respect to wound dehiscence and infection. Finally, it will compare the efficacy of serum or exudate ProCT/cytokine levels to established serum or exudate markers for infection in predicting the risk of wound infection and dehiscence. Participants of this study are wounded U.S. service members that sustain high-energy penetrating injuries to a single extremity and evac uated from Iraq, Afghanistan and an y future area of US combatoperations that are admitted to Walter Reed Army Medical Center (WRAMC) or National Naval Medical Cent er (NNMC). Loc al antibiotic delivery, high-pressure irrigation and wound evacuation dressings have advanced the treatment of high-energy penetrating injuries, but the decision to prim arily close or perform flap coverage of a wound remains subj ective. Considerable intra-observer variability e xists and des pite meticulous debridements and antibiotic therapy, some clean appearing wounds go on to dehiscence and become infected. Conver sely, because of this uncertainty, benig n appearing wounds may undergo unnecessary surgical debridements, exposing patients to additional anesthesia risks and surgical mo rbidity. A serum or exudate marker th at correlates with wound dehiscenc e and infection could prevent life and limb-threatening complications caused by prem ature wound closure and eliminate the morbidity associated with unnecessary debridement procedures.

BODY:

Project accomplishments include: continued development of in frastructure to implement AIM I, AIMS II, & III; hiring and tr aining of a second Research Assistant to assist with study supervision, s ample handling, and data entry; and c oordination with key personnel conducted inc luding correspondence with stud y consultants, study statistician, and critical cont acts at processing facilities , NMRC and VAMC. In addition, techniques for collection, processing and shipment of serum and exudate samples have been established and exec uted. Systems have been implement ed to ident ify, screen**,** and enroll incoming patients that meet incl usionary criteria. The following is the enrollment for the past year (1 January 2010 to 31 December 2010) 69 patients hav e been enrolled into the study; 36 patient enrolled form Nati onal Naval Medic al Center and 33 from Walter Reed army Medical Center for a total of 69 patients enrolled into this study. The total enrollment since this study has been initiated is 148 patients enrolled.

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KEY RESEARCH ACCOMPLISHMENTS:

Administrative and logistical matters.

a. Personnel.

1) Mr. Wesley Stepp, Research Assistant, resigned 19 July 2010.

2) Mr Felipe Lisboa replaced Mr. Stepp 2 September 2010.

3) Fred Gage PhD has supervised Research Assistants while continuing to provide study support through patient sampling and data collection.
4) Mr Samuel Han was terminated on 7 December 2010.

b. Database.
1) Data collected and data entered into study database.
2) Minor alteration of study database completed to enhanc e data manipulation ability during data analysis phase.

c. Equipment. New Apple I MAC was purchased for the WRAMC office.

d. Materials, supplies and consumables. Supplies and materials for NNMC, NMRC, VAMC, and WRAMC study requirements continue to be coordinated.

e. Institutional Review Board.

1) National Naval Medical Center (NNMC). There has been four (5) protocol amendments made by Responsible Cond uct of Research Department at NNMC.

A) Mr Samuel Han became an Associ ate Investigator to replace Ms Ceniceros.
B) Control tissue collection was added to the protocol.
C) Change in the Negative Pressure machine went from an older model to a newer model.
D) Mr Wesley Stepp resigned his position and was removed as Associat e Investigator from protocol.
E) Mr. Felipe Lisboa was added as an AI to the protocol.
F) Mr Samuel Han was removed as an AI from the study.

2) Walter Reed Army Medical Cent er (WRAMC) There has been four (4) protocol amendments by DCI at WRAMC this past year.
A) Mr Samuel Han was added as an Associate Investigator.
B) Dr. Fred O'Brien was added as an Associate Investigator.
C Mr Felipe Lisboa was added as an AI to the protocol.
D) Mr. Samuel Han was removed from the protocol as an AI.

3) Completion of NNMC IRB Cont inuing Review 18 March 2010 and renewed approval of NNM C protocol Informed Consent Forms (ICF) and Health Insurance Portability and Accountability Act (HIPAA) forms 02 APRIL 10.
4) Completion of WRAMC IRB Con tinuing Review and renewed approval of WRAMC protocol Informed Consent Fo rms (ICF) and Health Insurance Portability and Accountability Act (HIPPA) forms.

f. Subject Enrollment.

1) Collection of data for AIM II & III has been conducted.
2) Currently 148 subjects have been enrolled and consented into the study Protocol; 77 patients enrolled form National Naval Medical Center and 71 from Walter Reed army Medical Center.
3) Data collected has been continued to be entered into the study database.
4) Samples have been forwarded to VA and NMRC for analysis.

REPORTABLE OUTCOMES: Nothing to Report

CONCLUSION:
We have consented and collected data from 148 patients total since the study began, 69 the past year have been enrolled into the st udy at NNMC and WRAMC. We have started collecting control tissue from the autologous patella tissue transplants in the past year. We have not analyzed the data but continue to collect data and enroll patients.

REFERENCES:
Nothing to Report

APPENDICES:
Nothing to Report

SUPPORTING DATA:
Nothing to Report